

#2 1632  
**RECEIVED**  
AUG 29 2000  
TECH CENTER 1600/2900

**STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.**  
ATTORNEYS AT LAW  
1100 NEW YORK AVENUE, N.W., SUITE 600  
WASHINGTON, D.C. 20005-3934  
www.skgf.com  
PHONE: (202) 371-2600 FACSIMILE: (202) 371-2540

ROBERT GREENE STERNE  
EDWARD J. KESSLER  
JORGE A. GOLDSTEIN  
SAMUEL L. FOX  
DAVID K.S. CORNWELL  
ROBERT W. ESMOND  
TRACY-GENE G. DURKIN  
MICHAEL A. CIMBALA  
MICHAEL B. RAY  
ROBERT E. SOKOHL  
ERIC K. STEFFE  
MICHAEL Q. LEE

STEVEN R. LUDWIG  
JOHN M. COVERT\*  
LINDA E. ALCORN  
RAZ E. FLESHNER  
ROBERT C. MILLONIG  
MICHAEL V. MESSINGER  
JUDITH U. KIM  
TIMOTHY J. SHEA, JR.  
DONALD R. MCPHAIL  
PATRICK E. GARRETT  
STEPHEN G. WHITESIDE  
JEFFREY T. HELVEY\*

HEIDI L. KRAUS  
JEFFREY R. KURIN  
RAYMOND MILLIEN  
PATRICK D. O'BRIEN  
LAWRENCE B. BUGAISKY  
CRYSTAL D. SAYLES\*  
EDWARD W. YEE  
ALBERT L. FERRO\*  
DONALD R. BANOWIT  
PETER A. JACKMAN  
MOLLY A. MCCALL  
TERESA U. MEDLER

JEFFREY S. WEAVER  
KRISTIN K. VIDOVICH  
KENDRICK P. PATTERSON  
DONALD J. FEATHERSTONE  
GRANT E. REED  
VINCENT L. CAPUANO  
JOHN A. HARROUN\*  
MATTHEW M. CATLETT\*  
NATHAN K. KELLEY\*  
ALBERT J. FASULO II\*  
W. BRIAN EDGE\*

KAREN R. MARKOWICZ\*\*  
SUZANNE E. ZISKA\*\*  
BRIAN J. DEL BUONO\*\*  
ANDREA J. KAMAGE\*\*  
NANCY J. LEITH\*\*  
TARJA H. NAUKKARINEN\*\*

\*BAR OTHER THAN D.C.  
\*\*REGISTERED PATENT AGENTS

**WRITER'S DIRECT NUMBER:**  
(202) 371-2673  
**INTERNET ADDRESS:**  
JCOVERT@SKGF.COM

August 25, 2000

Assistant Commissioner for Patents  
Washington, D.C. 20231



Art Unit: 1632

Re: U.S. Utility Patent Application  
Appl. No. 09/580,463; Filed: May 26, 2000  
For: **Cytofectin Dimers and Methods of Use Thereof**  
Inventors: **WHEELER, Carl J.**  
Our Ref: 1530.0220001/JMC/MJD

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Information Disclosure Statement (in duplicate);
2. Form PTO-1449 (19 pages, citing 68 documents);
3. Sixty-eight (68) cited documents (AA1, AB1, AC1, AD1, AE1, AF1, AG1, AH1, AI1, AJ1, AK1, AL1, AR1, AS1, AT1, AA2, AR2, AS2, AT2, AR3, AS3, AT3, AR4, AS4, AT4, AR5, AS5, AT5, AR6, AS6, AT6, AR7, AS7, AT7, AR8, AS8, AT8, AR9, AS9, AT9, AR10, AS10, AT10, AR11, AS11, AT11, AR12, AS12, AT12, AR13, AS13, AT13, AR14, AS14, AT14, AR15, AS15, AT15, AR16, AS16, AT16, AR17, AS17, AT17, AR18, AS18, AT18, and AR19); and
4. One (1) return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Assistant Commissioner for Patents  
August 25, 2000  
Page 2

RECEIVED


AUG 29 2000

TECH CENTER 1600/2900

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036. A duplicate copy of this letter is enclosed.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

  
John M. Covert  
Attorney for Applicants  
Registration No. 36,688

JMC/MJD/rjv  
Enclosures

P:\USERS\MDOWD\1530\0220001\pto\ids.tm

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

WHEELER, Carl J.

Appl. No. 09/580,463

Filed: May 26, 2000

For: **Cytofectin Dimers and Methods of  
Use Thereof**



Art Unit: 1632

Examiner: *To Be Assigned*

Atty. Docket:  
1530.0220001/EKS/JMC/MJD

**Information Disclosure Statement**

Commissioner for Patents  
Washington, D.C. 20231

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

The Examiner's attention is directed to related, commonly assigned, co-pending U.S. Appl. No. 08/565,756, filed November 30, 1995, and U.S. Appl. No. 09/092,486, filed June 5, 1998. The identification of the above U.S. Patent Applications is not to be construed as a waiver of secrecy as to the application now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited application and the art cited therein during examination.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available

to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith. It is further understood that the Examiner will consider information that was cited or submitted to the U.S. Patent and Trademark Office in a prior application relied on under 35 U.S.C. § 120. 1138 OG 37, 38 (May 19, 1992).

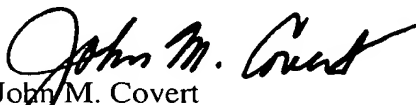
This Information Disclosure Statement is being filed within three months of the U.S. filing date or before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036. A duplicate copy of this pleading is enclosed.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

  
John M. Covert  
Attorney for Applicant  
Registration No. 38,759

Date: Aug. 25, 2000  
1100 New York Avenue, N.W.  
Suite 600  
Washington, D.C. 20005-3934  
(202) 371-2600

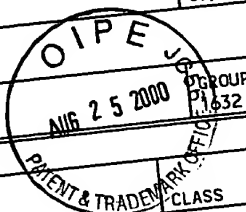
FORM PTO-1449  
INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.  
1530.0220001

APPLICATION NO.  
09/580,463

APPLICANT  
WHEELER, Carl

FILING DATE  
May 26, 2000



U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
AA1	4,713,339	12/15/1987	Levinson et al.	435	240.2	01/19/1983
AB1	4,897,355	01/30/1990	Eppstein et al.	435	240.2	01/07/1985
AC1	4,965,196	10/23/1990	Levinson et al.	435	691	01/19/1983
AD1	5,264,618	11/23/1993	Felgner et al.	560	224	04/19/1990
AE1	5,334,761	08/02/1994	Gebeyehu et al.	564	197	08/28/1992
AF1	5,459,127	10/17/1995	Felgner et al.	514	7	09/16/1993
AG1	5,580,859	12/03/1996	Felgner et al.	514	44	03/18/1994
AH1	5,589,466	12/31/1996	Felgner et al.	514	44	01/06/1995
AI1	5,676,954	10/14/1997	Brigham	424	450	05/08/1995
AJ1	5,693,622	12/02/1997	Wolff et al.	514	44	06/07/1995
AK1	5,703,055	12/30/1997	Felgner et al.	514	44	01/26/1994

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
✓ AL1	WO 94/29469	12/22/1994	WIPO			Yes No
AM1						Yes No
AN1						Yes No
AO1						Yes No
AP1						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

✓ AR	1	Agadjanyan, M.G., et al., "An HIV type 2 DNA Vaccine Induces Cross-Reactive Immune Responses against HIV type 2 and SIV," <i>AIDS Res. Hum. Retroviruses</i> 13(18):1561-1572 (December 1997).
✓ AS	1	Agadjanyan, M.G., et al., "DNA Plasmid Based Vaccination Against the Oncogenic Human T Cell Leukemia Virus Type 1," <i>Curr. Top. Microbiol. Immunol.</i> 226:175-192 (1998).
✓ AT	1	Altman-Hamamdizic, S., et al., "Expression of $\beta$ -galactosidase in mouse brain: utilization of a novel nonreplicative Sindbis virus vector as a neuronal gene delivery system," <i>Gene Ther.</i> 4(8):815-822 (August 1997).

EXAMINER

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO. 1530.0220001	APPLICATION NO. 09/580,463
	APPLICANT WHEELER, Carl	
	FILING DATE May 26, 2000	GROUP 1632

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA2	5,861,397	01/19/1999	Wheeler	514	247	10/03/1996
	AB2						
	AC2						
	AD2						
	AE2						
	AF2						
	AG2						
	AH2						
	AI2						
	AJ2						
	AK2						

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL2						Yes No
	AM2						Yes No
	AN2						Yes No
	AO2						Yes No
	AP2						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

✓	AR	2	Bangham, <i>et al.</i> , "Diffusion of Univalent Ions across the Lamellae," <i>J. Mol. Biol.</i> 23:238-252 (1965).
✓	AS	2	Behr, J.P., <i>et al.</i> , "Efficient gene transfer into mammalian primary endocrine cells with lipopolyamine-coated DNA," <i>Proc. Natl. Acad. Sci. U S A.</i> 86(18):6982-6986 (September 1989).
✓	AT	2	Boyer, J.D., <i>et al.</i> , "In vivo protective anti-HIV immune responses in non-human primates through DNA immunization," <i>J. Med. Primatol.</i> 25(3):242-250 (June 1996).

EXAMINER	DATE CONSIDERED
----------	-----------------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

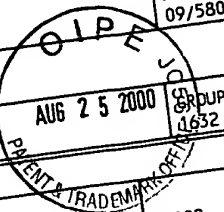
FORM PTO-1449  
INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.  
1530.0220001

APPLICANT  
WHEELER, Carl

FILING DATE  
May 26, 2000

APPLICATION NO.  
09/580,463



U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA3					
	AB3					
	AC3					
	AD3					
	AE3					
	AF3					
	AG3					
	AH3					
	AI3					
	AJ3					
	AK3					

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL3					Yes No
	AM3					Yes No
	AN3					Yes No
	AO3					Yes No
	AP3					Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

<input checked="" type="checkbox"/>	AR	3	Boyer, J.D., et al., "DNA Vaccination as Anti-Human Immunodeficiency Virus Immunotherapy in Infected Chimpanzees," J. Infect. Dis. 176(6):1501-1509 (December 1997).
<input checked="" type="checkbox"/>	AS	3	Boyer, J.D., et al., "Protection of chimpanzees from high-dose heterologous HIV-1 challenge by DNA vaccination," Nature Med. 3(5):526-532 (May 1997).
<input checked="" type="checkbox"/>	AT	3	Davis, H.L., "Plasmid DNA expression systems for the purpose of immunization," Curr. Opin. Biotechnol. 8(5):635-646 (October 1997).

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.



FORM PTO-1449  
INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.  
1530.0220001

APPLICATION NO.  
09/580,463

APPLICANT  
WHEELER, Carl

GROUP  
1632

FILING DATE  
May 26, 2000 AUG 25 2000

U.S. PATENT DOCUMENTS



EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA3					
	AB3					
	AC3					
	AD3					
	AE3					
	AF3					
	AG3					
	AH3					
	AI3					
	AJ3					
	AK3					

FOREIGN PATENT DOCUMENTS				CLASS	SUB-CLASS	TRANSLATION
EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY			Yes No
	AL3					Yes No
	AM3					Yes No
	AN3					Yes No
	AO3					Yes No
	AP3					Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

✓	AR	4	Davis, H.L., et al., "DNA-based immunization against hepatitis B surface antigen (HBsAg) in normal and HBsAg-transgenic mice," Vaccine 15(8):849-852 (June 1997).
/	AS	4	Davis, H.L., et al., "Direct gene transfer in skeletal muscle: plasmid DNA-based immunization against the hepatitis B virus surface antigen," Vaccine 12(16):1503-1509 (December 1994).
✓	AT	4	Davis, H.L., et al., "Immune-mediated destruction of transfected muscle fibers after direct gene transfer with antigen-expressing plasmid DNA," Gene Ther. 4(3):181-188 (March 1997).

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449

## INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.  
1530.0220001APPLICATION NO.  
09/580,463APPLICANT  
WHEELER, CarlFILING DATE  
May 26, 2000GROUP  
1632

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA3						
	AB3						
	AC3						
	AD3						
	AE3						
	AF3						
	AG3						
	AH3						
	AI3						
	AJ3						
	AK3						

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL3						Yes No
	AM3						Yes No
	AN3						Yes No
	AO3						Yes No
	AP3						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

✓	AR	5	DeBruyne, L.A., <i>et al.</i> , "Lipid-mediated gene transfer of viral IL-10 prolongs vascularized cardiac allograft survival by inhibiting donor-specific cellular and humoral immune responses," <i>Gene Ther.</i> 5(8):1079-1087 (August 1998).
✓	AS	5	Duzgunes, N., "Membrane fusion," in <i>Subcellular Biochemistry</i> . Roodyn, D.B., ed., Plenum Press, New York, Vol. 11, pp.195-286 (1985).
✓	AT	5	Etchart, N., <i>et al.</i> , "Class I-restricted CTL induction by mucosal immunization with naked DNA encoding measles virus haemagglutinin," <i>J. Gen. Virol.</i> 78 ( Pt 7):1577-1580 (July 1997).

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449  
INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.  
1530.0220001

APPLICANT  
WHEELER, Carl

FILING DATE  
May 26, 2000

APPLICATION NO.  
09/580,463

GROUP  
1632

AUG 25 2000

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA3					
	AB3					
	AC3					
	AD3					
	AE3					
	AF3					
	AG3					
	AH3					
	AI3					
	AJ3					
	AK3					

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
						Yes
						No
	AL3					Yes
						No
	AM3					Yes
						No
	AN3					Yes
						No
	A03					Yes
						No
	AP3					Yes
						No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

✓	AR	6	Felgner, P.L., et al., "Lipofection: A highly efficient, lipid-mediated DNA-transfection procedure," <i>Proc. Natl. Acad. Sci. U S A.</i> 84(21):7413-7417 (November 1987).
✓	AS	6	Felgner, J.H., "Separation and Quantitation of Cationic Liposome Components by High Performance Liquid Chromatography with Evaporative Light-Scattering Detection," <i>Pharm Res.</i> 14(9):1269-1271 (September 1997).
✓	AT	6	Felgner, P.L., "Nonviral Strategies for Gene Therapy," <i>Sci. Am.</i> 276:102-106 (June 1997).

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449  
INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.  
1530.0220001

APPLICATION NO.  
09/580,463

APPLICANT  
WHEELER, Carl

AUG 25 2000

GROUP  
1632

FILING DATE  
May 26, 2000

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA3					
	AB3					
	AC3					
	AD3					
	AE3					
	AF3					
	AG3					
	AH3					
	AI3					
	AJ3					
	AK3					

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
						Yes No
	AL3					Yes No
	AM3					Yes No
	AN3					Yes No
	AO3					Yes No
	AP3					Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

<input checked="" type="checkbox"/>	AR	Z	Fukunaga, M., et al., "Liposome Entrapment Enhances the Hypocalcemic Action of Parenterally Administered C," <i>Endocrinology</i> 115(2):757-761 (August 1984).
<input checked="" type="checkbox"/>	AS	Z	Gramzinski, R.M., et al., "Immune Response to a Hepatitis B DNA Vaccine in Aotus Monkeys: A Comparison of Vaccine Formulation, Route, and Method of Administration," <i>Mol Med.</i> 4(2):109-118 (February 1998).
<input checked="" type="checkbox"/>	AT	Z	Gregoriadis, G., et al., "Liposome-mediated DNA vaccination," <i>FEBS Lett.</i> 402(2-3):107-110 (February 1997).

DATE CONSIDERED

EXAMINER

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449  
INFORMATION DISCLOSURE STATEMENT

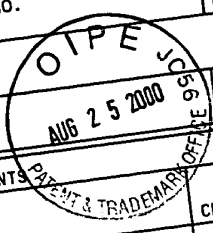
ATTY. DOCKET NO.  
1530.0220001

APPLICATION NO.  
09/580,463

APPLICANT  
WHEELER, Carl

FILING DATE  
May 26, 2000

GROUP  
1632



U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA3					
	AB3					
	AC3					
	AD3					
	AE3					
	AF3					
	AG3					
	AH3					
	AI3					
	AJ3					
	AK3					

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL3					Yes No
	AM3					Yes No
	AN3					Yes No
	AO3					Yes No
	AP3					Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

✓	AR	8	Hartikka, J., et al., "An Improved Plasmid DNA Expression Vector for Direct Injection into Skeletal Muscle," <i>Human Gene Ther.</i> 7(10):1205-1217 (June 1996).
✓	AS	8	Heppel, J., et al., "Development of DNA vaccines for fish: vector design, intramuscular injection and antigen expression using viral haemorrhagic septicaemia virus genes as model," <i>Fish and Shellfish Immunol.</i> 8:271-286 (1998).
✓	AT	8	Horn, et al., "Cancer Gene Therapy Using Plasmid DNA: Purification of DNA for Human Clinical Trials," <i>Human Gene Ther.</i> 6:656-673 (1995).

DATE CONSIDERED

EXAMINER

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449  
INFORMATION DISCLOSURE STATEMENT

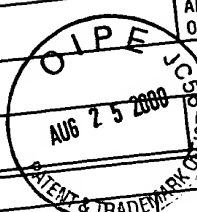
ATTY. DOCKET NO.  
1530.0220001

APPLICANT  
WHEELER, Carl

FILING DATE  
May 26, 2000

APPLICATION NO.  
09/580,463

CLASS  
GROUP  
9632



U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA3					
	AB3					
	AC3					
	AD3					
	AE3					
	AF3					
	AG3					
	AH3					
	AI3					
	AJ3					
	AK3					

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL3					Yes No
	AM3					Yes No
	AN3					Yes No
	AO3					Yes No
	AP3					Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

✓	AR	2	Ishii, N., et al., "Cationic Liposomes A Strong Adjuvant for a DNA Vaccine of Human Immunodeficiency Virus Type 1, " AIDS Res. Hum. Retroviruses 13(16):1421-1428 (November 1997).
✓	AS	2	Kim, S., et al., "Preparation of Multivesicular Liposomes," Biochim. Biophys. Acta 728:339-348 (1983).
✓	AT	2	Klavinskis, L.S, et al., "Mucosal immunization with DNA-liposome complexes," Vaccine 15(8):818-820 (June 1997).

DATE CONSIDERED

EXAMINER

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO. 1530.0220001	APPLICATION NO. 09/580,463
	APPLICANT WHEELER, Carl	
	FILING DATE May 26, 2000	GROUP 1632

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA3						
	AB3						
	AC3						
	AD3						
	AE3						
	AF3						
	AG3						
	AH3						
	AI3						
	AJ3						
	AK3						

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL3						Yes No
	AM3						Yes No
	AN3						Yes No
	AO3						Yes No
	AP3						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

✓	AR	10	Klavinskis, L.S., <i>et al.</i> , "Intranasal Immunization with Plasmid DNA-Lipid Complexes Elicits Mucosal Immunity in the Female Genital and Rectal Tracts," <i>J. Immunol.</i> 162(1):254-262 (January 1999).
✓	AS	10	Lodmell, D.L., <i>et al.</i> , "Gene gun particle-mediated vaccination with plasmid DNA confers protective immunity against rabies virus infection," <i>Vaccine</i> 16(2-3):115-118 (January-February 1998).
✓	AT	10	Lodmell, D.L., <i>et al.</i> , "DNA immunization protects nonhuman primates against rabies virus," <i>Nature Med.</i> 4(8):949-952 (August 1998).

EXAMINER	DATE CONSIDERED
----------	-----------------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449  
INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.  
1530.0220001

APPLICATION NO.  
09/580,463

APPLICANT  
WHEELER, Carl

FILING DATE  
May 26, 2000

GROUP  
1632

OTPE  
AUG 25 2000

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA3					
	AB3					
	AC3					
	AD3					
	AE3					
	AF3					
	AG3					
	AH3					
	AI3					
	AJ3					
	AK3					

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
						Yes
						No
	AL3					Yes
						No
	AM3					Yes
						No
	AN3					Yes
						No
	AO3					Yes
						No
	AP3					Yes
						No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

✓	AR	11	Mayer, L.D., et al., "Vesicles of variable sizes produced by a rapid extrusion procedure," <i>Biochim. Biophys. Acta.</i> 858(1):161-168 (June 1986).
✓	AS	11	Mayhew, E., et al., "Characterization of Liposomes Prepared Using a Microemulsifier," <i>Biochim. Biophys. Acta.</i> 775(2):169-174 (August 1984).
✓	AT	11	Nishizawa, et al., "Anion Recognition by Urea and Thiourea Groups: Remarkably Simple Neutral Receptors for Dihydrogenphosphate," <i>Tetrahedron Lett.</i> 36(36):6483-6486 (1995).

DATE CONSIDERED

EXAMINER

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.



FORM PTO-1449

## INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.  
1530.0220001APPLICATION NO.  
09/580,463APPLICANT  
WHEELER, CarlFILING DATE  
May 26, 2000GROUP  
1632

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA3						
	AB3						
	AC3						
	AD3						
	AE3						
	AF3						
	AG3						
	AH3						
	AI3						
	AJ3						
	AK3						

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL3						Yes No
	AM3						Yes No
	AN3						Yes No
	AO3						Yes No
	AP3						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

✓	AR	<u>12</u>	Okada, E., <i>et al.</i> , "Intranasal Immunization of a DNA Vaccine with IL-12- and Granulocyte-Macrophage Colony-Stimulating Factor (GM-CSF)-Expressing Plasmids in Liposomes Induces Strong Mucosal and Cell-Mediated Immune Responses Against HIV-1 Antigens," <i>J. Immunol.</i> 159(7):3638-3647 (October 1997).
✓	AS	<u>12</u>	Olson, F., <i>et al.</i> , "Preparation of Liposomes of Defined Size Distribution by Extrusion Through Polycarbonate Membranes," <i>Biochim. Biophys. Acta.</i> 557(1):9-23 (October 1979).
✓	AT	<u>12</u>	Qin, Y.J., <i>et al.</i> , "Gene Suture--A Novel Method for Intramuscular Gene Transfer and its Application in Hypertension Therapy," <i>Life Sci.</i> 65(21):2193-2203 (1999).

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

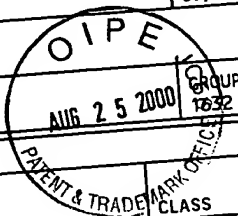
FORM PTO-1449  
INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.  
1530.0220001

APPLICATION NO.  
09/580,463

APPLICANT  
WHEELER, Carl

FILING DATE  
May 26, 2000



## U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA3					
	AB3					
	AC3					
	AD3					
	AE3					
	AF3					
	AG3					
	AH3					
	AI3					
	AJ3					
	AK3					

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
						Yes
						No
	AL3					Yes
						No
	AM3					Yes
						No
	AN3					Yes
						No
	AO3					Yes
						No
	AP3					Yes
						No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

✓	AR	13	Sambrook, et al., in <i>Molecular Cloning. A Laboratory Manual</i> , 2 <sup>nd</sup> ed., Cold Spring Harbor Laboratory Press, p. A-2 (1989).
✓	AS	13	Sasaki, S., et al., "Monophosphoryl Lipid A Enhances Both Humoral and Cell-Mediated Immune Responses to DNA Vaccination Against Human Immunodeficiency Virus Type 1," <i>Infect. Immun.</i> 65(9):3520-3528 (September 1997).
✓	AT	13	Sasaki, S., et al., "Adjuvant effect of Ubenimex on a DNA vaccine for HIV-1," <i>Clin. Exp. Immunol.</i> 111(1):30-35 (January 1998).
EXAMINER			DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449

## INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.  
1530.0220001APPLICATION NO.  
09/580,463APPLICANT  
WHEELER, CarlFILING DATE  
May 26, 2000

AUG 25 2000

GROUP  
1632

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA3						
	AB3						
	AC3						
	AD3						
	AE3						
	AF3						
	AG3						
	AH3						
	AI3						
	AJ3						
	AK3						

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL3						Yes No
	AM3						Yes No
	AN3						Yes No
	AO3						Yes No
	AP3						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

✓	AR	<u>14</u>	Sasaki, S., <i>et al.</i> , "Induction of Systemic and Mucosal Immune Responses to Human Immunodeficiency Virus Type 1 by a DNA Vaccine Formulated with QS-21 Saponin Adjuvant via Intramuscular and Intranasal Routes," <i>J. Virol.</i> 72(6):4931-9 (June 1998).
✓	AS	<u>14</u>	Schrijver, R.S., <i>et al.</i> , "Immunization of cattle with a BHV1 vector vaccine or a DNA vaccine both coding for the G protein of BRSV," <i>Vaccine</i> 15(17-18):1908-1916 (December 1997).
✓	AT	<u>14</u>	Stephan, D.J., <i>et al.</i> , "A New Cationic Liposome DNA Complex Enhances the Efficiency of Arterial Gene Transfer <i>In Vivo</i> ," <i>Human Gene Ther.</i> 7(15):1803-1812 (October 1996).

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449

## INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.  
1530.0220001APPLICATION NO.  
09/580,463APPLICANT  
WHEELER, CarlFILING DATE  
May 26, 2000GROUP  
1632

U.S. PATENT DOCUMENT

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA3					
	AB3					
	AC3					
	AD3					
	AE3					
	AF3					
	AG3					
	AH3					
	AI3					
	AJ3					
	AK3					

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL3					Yes No
	AM3					Yes No
	AN3					Yes No
	AO3					Yes No
	AP3					Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

<input checked="" type="checkbox"/>	AR	15	Strauss, J.K., et al., "DNA bending by hexamethylene-tethered ammonium ions," <i>Proc. Natl. Acad. Sci. U S A.</i> 93(18):9515-9520 (September 1996).
<input checked="" type="checkbox"/>	AS	15	Szoka, F., et al., "Procedure for preparation of liposomes with large internal aqueous space and high capture by reverse-phase evaporation," <i>Proc. Natl. Acad. Sci. U S A.</i> 75(9):4194-4198 (September 1978).
<input checked="" type="checkbox"/>	AT	15	Ulmer, J.B., et al., "Heterologous Protection Against Influenza by Injection of DNA Encoding a Viral Protein," <i>Science</i> 259(5102):1745-9 (March 1993).
			DATE CONSIDERED

EXAMINER

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO. 1530.0220001	APPLICATION NO. 09/580,463
	APPLICANT WHEELER, Carl	
	FILING DATE May 26, 2000	GROUP 1632

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA3						
	AB3						
	AC3						
	AD3						
	AE3						
	AF3						
	AG3						
	AH3						
	AI3						
	AJ3						
	AK3						

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL3						Yes No
	AM3						Yes No
	AN3						Yes No
	AO3						Yes No
	AP3						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

X	AR	16	Ulmer, J.B., <i>et al.</i> , "DNA Vaccines for Bacteria and Viruses," <i>Adv. Exp. Med. Biol.</i> 397:49-53 (1996).
X	AS	16	Ulmer, J.B., <i>et al.</i> , "DNA vaccines," <i>Curr. Opin. Immunol.</i> 8(4):531-536 (August 1996).
X	AT	16	Ulmer, J.B., <i>et al.</i> , "Generation of MHC class I-restricted cytotoxic T lymphocytes by expression of a viral protein in muscle cells: antigen presentation by non-muscle cells," <i>Immunology</i> 89(1):59-67 (September 1996).

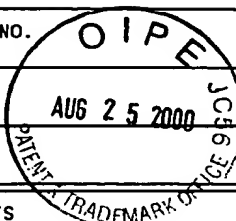
EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449

## INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.  
1530.0220001APPLICANT  
WHEELER, CarlFILING DATE  
May 26, 2000APPLICATION NO.  
09/580,463GROUP  
1632

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA3						
	AB3						
	AC3						
	AD3						
	AE3						
	AF3						
	AG3						
	AH3						
	AI3						
	AJ3						
	AK3						

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL3						Yes No
	AM3						Yes No
	AN3						Yes No
	AO3						Yes No
	AP3						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

X	AR	17	Ulmer, J.B., et al., "Toward the development of DNA vaccines," <i>Curr. Opin. Biotechnol.</i> 7(6):653-658 (December 1996).
X	AS	17	Vahlsing, H.L., et al., "Immunization with plasmid DNA using a pneumatic gun," <i>J. Immunol. Methods</i> 175(1):11-22 (September 1994).
X	AT	17	Vanderzanden, L., et al., "DNA Vaccines Expressing either the GP or NP Genes of Ebola Virus Protect Mice from Lethal Challenge," <i>Virology</i> 246(1):134-44 (June 1998).

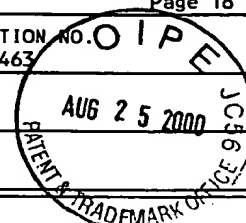
EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449

## INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.  
1530.0220001APPLICATION NO.  
09/580,463APPLICANT  
WHEELER, CarlFILING DATE  
May 26, 2000GROUP  
1632

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA3						
	AB3						
	AC3						
	AD3						
	AE3						
	AF3						
	AG3						
	AH3						
	AI3						
	AJ3						
	AK3						

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL3						Yes No
	AM3						Yes No
	AN3						Yes No
	AO3						Yes No
	AP3						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

X	AR	18	Wang, B., <i>et al.</i> , "Mucosal immunization with a DNA vaccine induces immune responses against HIV-1 at a mucosal site," <i>Vaccine</i> 15(8):821-825 (June 1997).
X	AS	18	Wheeler, C.J., <i>et al.</i> , "A novel cationic lipid greatly enhances plasmid DNA delivery and expression in mouse lung," <i>Proc. Natl. Acad. Sci. U S A.</i> 93(21):11454-11459 (October 1996).
X	AT	18	Wheeler, C.J., <i>et al.</i> , "Converting an alcohol to an amine in a cationic lipid dramatically alters the co-lipid requirement, cellular transfection activity and the ultrastructure of DNA-cytoskeleton complexes," <i>Biochim. Biophys. Acta</i> 1280(1):1-11 (April 1996).

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449  
INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.  
 1530.0220001

APPLICATION NO.  
 09/580,463

APPLICANT  
 WHEELER, Carl

GROUP  
 1632

FILING DATE  
 May 26, 2000



U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA3						
	AB3						
	AC3						
	AD3						
	AE3						
	AF3						
	AG3						
	AH3						
	AI3						
	AJ3						
	AK3						

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
							Yes No
	AL3						Yes No
	AM3						Yes No
	AN3						Yes No
	AO3						Yes No
	AP3						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

W	AR	19	Yokoyama, M., et al., "DNA immunization: Effects of vehicle and route of administration on the induction of protective antiviral immunity," <i>FEMS Immunol. Med. Microbiol.</i> 14(4):221-230 (July 1996).
	AS	19	
	AT	19	

DATE CONSIDERED

EXAMINER

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.